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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/449,532 | 11/29/99 | LURIA | S 916/13 |

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| EXAMINER | |
|---|---|
| LEFFERS JR.G | |
| **ART UNIT** | **PAPER NUMBER** |
| 1636 | 3 |

**DATE MAILED:** 06/20/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/449,532 | Luria, Sylvie |
| **Examiner** | **Group Art Unit** |
| Gerald G. Leffers Jr. | 1636 |

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *1-134* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-134* are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-23 and 69-91, drawn to an expression system and its use for the detection and isolation of a polypeptide capable of regulating a transduction pathway, classified in class 435, subclass 6.

II. Claims 24-48 and 92-113, drawn to an expression system and its use for the detection and isolation of a polypeptide capable of regulating a transduction pathway, classified in class 435, subclass 6.

III. Claims 49-68 and 114-134, drawn to an expression library and its use for detecting a polypeptide capable of regulating a transduction pathway, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-III are biologically and functionally different and distinct from each other and thus one does not render the others obvious. The methods of Groups I-III comprise different vector/gene/regulatory element combinations which are structurally and functionally distinct from one another: a two vector system in which the first vector comprises a cis-regulatory element responsive to the target signal transduction pathway operatively linked to

a reporter gene and a second construct comprising an unknown polypeptide operatively linked to a promoter (Group I), a two vector system in which the first construct comprises cis-regulatory element responsive to the target signal transduction pathway which is operatively linked to the coding sequence for a known transactivator and a second construct in which a cis-regulatory element responsive to the known transactivator is operatively linked to the coding sequence for an unknown polypeptide as well as the coding sequence for a reporter (Group II) and a single vector system in which the coding sequence for an unknown polypeptide and a reporter polypeptide are both operatively linked to a cis-regulatory element which is responsive to the target signal transduction pathway (Group III). The methods of the different Groups have different end results: identification of a polypeptide whose expression affects the expression of a reporter molecule directly linked to a transduction pathway-responsive element (Group I), identification of a polypeptide whose expression ultimately affects its own expression and that of a reporter gene in an "amplification" mechanism whereby the polypeptide's effects on a transduction pathway are mediated via a transduction pathway-responsive cis element operatively linked to the coding sequence of a known transactivator (Group II) and identification of a polypeptide whose expression directly modulates its own expression and that of a coding sequence for a reporter, both of which are operatively linked to a transduction pathway-responsive cis element (Group III). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and the non-patent literature search required for each of Groups I-III is not required for each of the other Groups (e.g. use of compatible dual vector constructs in a signal transduction pathway-reporter system (Group I), use of a known transactivator polypeptide as part of a signal transduction pathway-reporter system (Group II) and use of a single vector, "signal amplification" approach as part of a signal transduction pathway-reporter system (Group III), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

**Group I Species I** (reporter types), pick one of the claim pairs from the group consisting of: claims 2/70, 3/71 and 5/73. If the claim pair of 3/71 are elected, please pick one member from the Markush groups of claims 4 and 72 and make them consistent with one another. **Group I Species II** (transcriptional or translational regulatory elements/factors), please pick one member of each of the Markush groups of claims 11-12 and 79-80 and make them consistent with one another. **Group I Species III** (polypeptide types), please pick one member of the Markush groups of claims 22 and 90 and make them consistent with one another.

**Group II Species I** (reporter types), please pick one of claims 28, 29 and 31. If claim 29 is elected, please elect one member of the Markush group of claim 30. **Group II Species II** (transcriptional or translational regulatory elements/factors), please pick one member of each of

the Markush groups of claims 36-37 and 101-102 and make them consistent with one another. **Group II Species III** (polypeptide types), please pick one member of the Markush groups of claims 47 and 112, making them consistent with one another.

**Group III Species I** (reporter types), please pick one of the claims pairs from the group consisting of: claims 50/115, 51/116 and 53/118. If the pair of 51/116 is elected, then choose one member of each of the Markush groups of claims 52 and 117, making them consistent with one another. **Group III Species II** (transcriptional or translational regulatory elements/factors), pick one member of each of the Markush groups of claims 56-57 and 122-123, making the choices consistent with one another. **Group III Species III** (polypeptide types), please pick one member of each of the Markush groups of claims 67 and 133, making them consistent with one another.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Claims 1 & 69 are generic for Group I Species I. Claims 1, 11-12, 69 and 79-80 are generic for Group I Species II. Claims 1, 22, 69 and 90 are generic for Group I Species III. Claims 24 and 92 are generic for Group II Species I. Claims 24, 36-37, 92 and 101-102 are generic for Group II Species II. Claims 24, 47, 92 and 112 are generic for Group II Species III. Claims 49 and 114 are generic for Group III Species I. Claims 49, 56-57, 114 and 122-123 are generic for Group III Species II. Claims 49, 67, 114 and 133 are generic for Group III Species III.

A telephone call was made to Robert Sheinbein on or about 3/30/00 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Leffers, Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than 24 hours after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. George Elliott, can be reached on (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

GLJ

G. Leffers, Jr.
Patent Examiner
Art Unit 1636

June 16, 2000

TERRY MCKELVEY
PRIMARY EXAMINER